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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	VPHAR1460-2	2878

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EXAMINER	
HARTLEY, MICHAEL G	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,783	DESAI ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-75,101-105,107,108 and 122-133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-75,101-105,107,108 and 122-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/2004 has been entered.

Response to Amendment

The amendment filed 8/6/2004 has been entered.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73, 101-103, 107, 108 and 122-132 are rejected under 35 U.S.C. 102(e) as being anticipated by Violante (US 5,741,522).

Violante discloses an article of manufacture comprising non-crystalline (i.e., amorphous) ultra-small particles of a drug, which are coated with a protein, see abstract and example III. In example III, IDE porous (amorphous, solid) particles are coated with human serum albumin (note: the IDE particles are within the scope of "drug" nanoparticles, as IDE is a CT contrast agent, see column 7, lines 43+). Violante also teaches that various therapeutic agents (e.g., anti-neoplastics, 5fdU, etc.) may be used in the particles, see column 7, lines 55+, column 9 and column 11, lines 45+. The particles are clearly within the scope of nanoparticles as claimed, see claim 2. Violante teaches that the particles are suspended in various pharmaceutical carriers, for parenteral administration, see column 11, lines 42+, which would render the "suitable for" the various administrations set forth as "intended use" recitation in claims 122-132. Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 73, 101-103, 107, 108 and 122-132 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiowitz (US 5,721,961).

Mathiowitz discloses an article of manufacture comprising amorphous particles of a drug, which is coated with a protein, see abstract and column 3. The particles include nanoparticles, see columns 3. The particles are amorphous, as they are of irregular shape

and/or semi-porous, see column 3 and examples 1-3, which set forth insulin particles coated with protein. The particles may include various drugs, anesthetics, etc., see column 8. Mathiowitz teaches that the particles are suspended in various pharmaceutical carriers, for parenteral administration, see columns 7-8 and examples 1-4, which would render the "suitable for" the various administrations set forth as "intended use" recitation in claims 122-132. Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claims 73, 102, 107, 108 and 122-132 are rejected under 35 U.S.C. 102(e) as being anticipated by End (US 5,700,471).

End discloses an article of manufacture comprising amorphous drug nanoparticles, see abstract. The nanoparticles are generally below 1 um, see columns 1-2. The nanoparticles are also coated with a protein, e.g., gelatin, see examples 1-2. End teaches that the particles are suspended in a pharmaceutical carrier (e.g., water), see example 7, which would render the "suitable for" the various administrations set forth as "intended use" recitation in claims 122-132. Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73, 74, 104 and 133 are rejected under 35 U.S.C. 102(e) as being anticipated by Violante (US 5,741,522) in view of Unger (US 6,143,276).

Violante discloses an article of manufacture comprising non-crystalline (i.e., amorphous) ultra-small particles of a drug, which is coated with a protein, see abstract and example III, as set forth above.

Violante teaches that various therapeutic agents may be used in the particles, but fails to specifically recite, taxol, cyclosporin or anesthetics, as claimed.

Unger discloses composition comprising a drug (bioactive agent) and a stabilizing material, see column 1-2. The stabilizing material may be a protein, such as, albumin, see column 3, lines 5-7. Unger teaches that nanoparticles size provides the advantage of targeted intravascular use, see column 26, lines 30-33. Various drugs may be employed in the nanospheres, including hormones, cyclosporin, taxol, anesthetics, etc., see columns 36-37.

It would have been obvious to one of ordinary skill in the art to employ various drugs, such as, taxol, cyclosporin, anesthetics, etc., as the drug (generic) in the nanoparticles disclosed by Violante because such drugs are well known in the art to be useful in nanoparticle form for targeted delivery for treating various diseases. One of ordinary skill in the art would have been motivated to employ various drugs in the

invention of Violante, such as those taught by Unger in order to treat various conditions with the therapeutic nanoparticles of Violante.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Violante (US 5,741,522) in view of Unger (US 6,143,276).as applied to claims 73, 74, 104 and 133 above, and further in view of Jones (US 5,731,355).

Violante discloses drug nanoparticles coated with albumin and teaches the use of various drugs, while, Unger teaches drug nanoparticles wherein various drugs may be employed, including anticancer agents, anesthetics, etc., but fails to specifically disclose that the anesthetic is propofol.

Jones teaches that propofol is a well-known and highly successful anesthetic, see column 1.

It would have been obvious to one of ordinary skill in the art to use propofol as the drug in the invention of Violante which generically teaches the use of various therapeutics because Unger teaches that various drugs, including, anesthetics, may be used in nanoparticles and because propofol is known as a highly successful anesthetic in the art, as shown by Jones.

Claims 73-75, 101-104, 107 and 108 and 122-133 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (US 5,439,686) in view of Westesen (US 6,197,349).

Desai discloses compositions comprising a protein that contain "particles of taxol" see abstract. Particles of taxol are prepared in example 1 and are most preferably

less than 1 micron, which encompasses nanoparticles. Exemplified proteins are albumin and the drug is taxol, see column 6, lines 35+ and examples 2, 4 and 9. The particle size includes 0.1 microns, which is 100 nm, see column 9, lines 15-16. The particles are for paternal administration, see column 3. Desai also teaches that other drugs may be employed in the particles, i.e., cyclosporin, etc., see example 12.

Desai is silent as to whether or not the drug nanoparticles are amorphous.

Westesen teaches drug nanoparticles for the delivery of various drugs, taxol, etc., see abstract and column 13. Westesen also teaches that the drug nanoparticles should be amorphous because an amorphous state provides a higher solubility and a faster dissolution of the drug, see column 5, lines 45-57.

It would have been obvious to one of ordinary skill in the art to form the drug nanoparticles disclosed by Desai in amorphous form because it is well known in the art of drug nanoparticles that the amorphous state provides a higher solubility and a faster dissolution of the drug, as shown by Westesen.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75 and 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 75, the recitation of "free of surfactants" is confusing because the base claim states that the particles are coated with albumin and such a coating would be within

the scope of surfactant. It is unclear what is being excluded by the recitation of "free of surfactants" in this claim.

In claim 102 the recitation of "liquid" is confusing because it defines a nanoparticles which is coated with albumin and is amorphous and it is unclear how a liquid can satisfy such requirements.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

10/14/2004